

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 0 861 632 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
02.09.1998 Bulletin 1998/36

(51) Int. Cl.⁶: **A61B 17/00, A61B 17/04**

(21) Application number: **98101448.3**

(22) Date of filing: **28.01.1998**

(84) Designated Contracting States:
**AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC
NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

(30) Priority: **30.01.1997 JP 16300/97**

(71) Applicant: **Nissho Corporation**
Osaka-shi, Osaka-fu, 531-8510 (JP)

(72) Inventors:
• **Koike, Kazuyuki**
Tokyo-to (JP)

• **Kishigami, Yoshikazu**
Shiga-ken (JP)
• **Miyagawa, Katsuya**
Takashima-gun, Shiga-ken (JP)

(74) Representative:
Weisert, Annekäte, Dipl.-Ing. Dr.-Ing. et al
Patentanwälte
Kraus Weisert & Partner
Thomas-Wimmer-Ring 15
80539 München (DE)

(54) Catheter assembly for intracardiac suture

(57) Disclosed is an assembly catheter for intracardiac suture, comprising: a hooking catheter 3 provided with a suture-hooking means 32 at a distal end and with a manipulating element (grip) 33 at a proximal end; a piercing catheter 2 having lumen 21 for movably holding the hooking catheter 3 and provided with a piercing needle 25 at a distal end and with a hemostatic valve 24 as the hemostatic means at a proximal end, the distal portion 28 of the piercing catheter adjacent to the piercing needle 25 being easily bendable; a sheath 1 having a lumen 11 for movably holding the piercing catheter 2 and provided with a hemostatic valve 14 as the hemostatic means at a proximal end; and a catheter-bending means 4 connected to the piercing needle 25 of the piercing catheter 2; in which the distal portion 28 of the piercing catheter 2 can be bent by the catheter-bending means 4. The catheter assembly is applicable to intracardiac suture for various configurations of ASD.

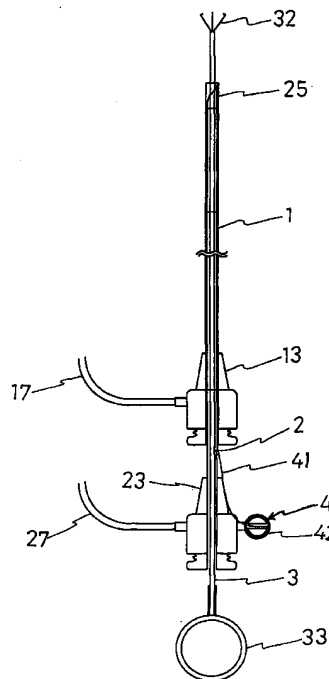


FIG. 1

EP 0 861 632 A1

Description

FIELD OF THE INVENTION

The present invention relates to a catheter assembly for intracardiac suture and, more particularly, to a catheter assembly for intracardiac suture procedure suitable for surgical technique, so-called transcatheter atrioseptopexy, in which a sewing device is inserted into a peripheral blood vessel and manipulated into the heart by cardiocatheterization under cross-sectional echocardiography to sew an atrial septal defect (ASD) by direct suturing.

BACKGROUND OF THE INVENTION

In general, congenital cardiac diseases such as ASD have been treated by surgical operation. As a matter of course, such a surgical operation includes not only treatment of the affected part but also thoracotomy or laparotomy and causes a lot of damage to a patient. In particular, it causes serious damage to child patients who are poor in physical strength.

Recently, a non-operative method for occlusion of atrial septal defects has been developed, in which a cardiocatheter is transvascularly inserted into the heart. This method is known as a percutaneous transluminal therapeutic catheterization, and the first clinical success in this method has been reported in 1976 by King and Mill. In the King et al's method, an atrial septal defect is closed by introducing a pair of umbrella-like members for the left atrium and the right atrium into the both atria with an insertion tool composed of a double-layered catheter and a core wire coaxially arranged therein, placing the members on the opposite sides of the defect, and locking them together at a central hub which crosses the defect.

However, this method requires use of a very large-sized insertion tool and hard umbrella-like members, thus making it impossible to apply it to children, especially to preschool children. For this reason, as a result of efforts to miniaturize such a device, Rashkind developed a single-umbrella type plug having a hook and succeeded in clinical application to a child in 1977. However, this method has such a defect that the plug is hooked on an unintended side of the heart because of being provided with the hook. Once the umbrella-like member is opened, it is impossible to change the hooked position as well as to draw back the device from the heart. This requires an emergent surgical operation when the plug is hooked on an unintended side of the heart. In order to overcome such disadvantages, Rashkind had further developed a plug comprising two umbrella-shaped occluders having eight stainless steel struts and being connectable to each other. The device has been put into clinical use widely for occlusion of patent ductus arteriosus.

Japanese unexamined patent application No. 5-

237128 filed by James E. Lock, et al. discloses an interatrial occlusion device comprising two umbrella-shaped members composed of eight stainless steel struts like in the Rashkind's device, each strut being provided at a central part thereof with a spring coil. This device is firmly fixed to the thin interatrial septum by closely adhering two umbrella-shaped members to each other in the overlapping state. This device is called as a clam shell-shaped interatrial occluder because of its configuration similar to that of a clam being a bivalve. The procedure is carried out by inserting an elongated sheath with a thickness of 11 French through the femoral vein. This device has been widely used for closing atrial septal defects by means of percutaneous transluminal therapeutic catheterization since the device can be applied to patients with a weight of 8 kg and above.

However, there is a limitation to the applications of these occlusion plugs since only the occlusion plugs with a uniform shape is prepared for various configurations of atrial septal defects and since the occlusion of a defective opening or hole requires use of an occlusion plug twice the size of the defective opening or hole, these devices can be applied only to a relatively small defective openings or holes present in the central part of the atrioventricular septum. In addition, there is a fear of bad effects due to use of occlusion plugs since there is no data on long-term use of the occlusion plug left in the heart.

The present inventor have already proposed a catheter assembly for intracardiac suture, which is applicable to various configurations of ASD and can percutaneously sew and closed ASD, as disclosed in Japanese unexamined patent application No. 7-269916. Using this catheter assembly, an atrial septal defective opening or hole is closed by piercing the piercing catheter into the atrial septum and transferring the suture with the suture-hooking catheter. However, this catheter assembly is required to transfer the suture with the suture-hooking catheter every time the piercing catheter has pierced, and the operation with this catheter assembly is complicated. For this reason, further improvements in this assembly have been desired.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to provide a catheter assembly for intracardiac suture operation, which is suitable for various configurations of ASD, can be handled with ease and can surely sew and close the defective opening or hole.

According to the present invention, the above object is achieved by providing a catheter assembly for intracardiac suture operation comprising:

a hooking catheter provided with a suture-hooking means at a distal end thereof and with a manipulating element for manipulating the suture-hooking means at a proximal end thereof;

a piercing catheter having a lumen for movably holding the hooking catheter and provided with a piercing needle at a distal end thereof and with a hemostatic means at a proximal end thereof, the distal portion of said piercing catheter adjacent to the piercing needle being easily bendable;

a sheath having lumen for movably holding the piercing catheter and provided with a hemostatic means at a proximal end thereof; and

a catheter-bending means connected to the piercing needle of the piercing catheter;

wherein the distal portion of said piercing catheter can be easily bent by said catheter-bending means and the bent distal portion can be held in such a state by said catheter bending means.

The suture-hooking means may be composed of two or more super-elastic metal wires and formed into an L-shaped hook by inwardly bending super-elastic metal wires at the distal end portion thereof, and wherein said suture-hooking members being extended outwardly at the proximal end portion and bent inwardly at the distal portion so that the L-shaped hook do not intersect each other when the suture-hooking means is put out of the piercing catheter. Preferably the distal end portion of the suture-hooking means is bent at a bend angle within the range of 80 and 100 degrees. The piercing catheter and the sheath are provided at the respective proximal ends with a side injection channel for injecting heparinized physiological saline into the suturing site. Generally, the catheter-bending means comprises a wire and a wire take-up means provided at the proximal end of the sheath or the piercing catheter, and wherein the distal end of the wire is fitted to the proximal end portion of the piercing needle, while the proximal end of the wire passes through the space between the piercing catheter and the sheath to be put out of the proximal end of the sheath, and is connected to the wire take-up means.

The above and other objects and features of the present invention will become clear from the following description taken in conjunction with the preferred embodiments thereof with reference to the accompanying drawings which are given by way of illustration only, and thus are not limitative of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view of a catheter assembly for intracardiac suture according to the present invention.

Fig. 2 shows the catheter assembly of Fig. 1, of which the distal end has been bent at 180 degrees.

Fig. 3 is a sectional view of the sheath of the catheter assembly of Fig. 1.

Fig. 4 is a sectional view of the piercing catheter of the catheter assembly of Fig. 1.

Fig. 5 is a sectional view of the hooking catheter of

the catheter assembly of Fig. 1.

Fig. 6 is a schematic view of the combination of the piercing catheter and the sheath of the catheter assembly of Fig. 1.

Fig. 7 is a schematic view of the combination of Fig. 6, in which a predetermined length of the piercing needle of the piercing catheter has been stuck out of the sheath.

Figs. 8 to 12 are explanatory views illustrating intracardiac suture with the catheter assembly of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Preferred embodiments of the invention are described herein under with reference to the drawings attached hereto.

Referring now to Figs. 1 to 7, there is shown the catheter assembly for intracardiac suture according to the present invention comprising:

a hooking catheter 3 having a suture-hooking means 32 at a distal end and a manipulating element (grip) 33 at a proximal end;

a piercing catheter 2 having a lumen 21 for movably holding the hooking catheter 3 and a piercing needle 25 at a distal end and a hemostatic valve 24 as the hemostatic means at a proximal end, the distal portion 28 of the piercing catheter adjacent to the piercing needle 25 being easily bendable;

a sheath 1 having a lumen 11 for movably holding the piercing catheter 2 and a hemostatic valve 14 as the hemostatic means at a proximal end; and a catheter-bending means 4 connected to the piercing needle 25 of the piercing catheter 2;

wherein the distal portion 28 of the piercing catheter 2 can be bent by the catheter-bending means 4, as in Fig. 2.

As in Fig. 3, the sheath 1 is composed of a sleeve 12 with a lumen 11 for free insertion of the piercing catheter 2. The sleeve 12 is provided at its proximal end with a connector 13. The connector 13 has an inlet of the lumen 11, i.e., an insertion hole 145 for the piercing catheter 2, and is provided with the hemostatic means or a hemostatic valve 14 to prevent leakage of the blood during surgical operation. The hemostatic valve 14 is not limited in construction. For example, as in Fig. 3, the hemostatic valve 14 is composed of a screw-hole or nut-like means 144 provided in the rear end of the connector 13, and a packing 141 with a central through-hole 142, and a bolt-like member 143 engaged with the screw-hole 144. By driving the bolt-like member 143 in, the packing 141 is pressed against the bottom wall of the screw-hole 144 to adjust the inner diameter of the through-hole 142. Further, the connector 13 is generally provided with a side injection channel 16 for injecting

heparinized physiological saline into the suturing site to prevent occurrence of blood coagulation during surgical operation, and the side injection channel 16 is connected to a side injection tube 17. Preferably the distal portion of the sleeve 12 is made bendable in correspondence with the bending of the piercing catheter 2.

As the material for the sleeve 12 of the sheath 1, there may be used synthetic resins such as fluororesins (e.g., polytetrafluoroethylene), polypropylene, polyethylene, polyamide, polyethylene terephthalate, polyurethane and the like, and also meshed or coiled stainless steel (e.g., SUS 304). The connector 13 is generally made from a synthetic resin that includes polypropylene, ABS (acrylonitrile-butadiene-styrene) resins, polyvinyl chloride, polyethylene, polyethylene terephthalate and the like, or even from a metal such as stainless steel, brass or the like. The packing 141 of the hemostatic valve 14 may be made from a material with rubber elasticity, for example, synthetic rubber, such as silicone rubber or isoprene rubber, or natural rubber. As the material for the bolt-like means, there may be used synthetic resins such as polycarbonate, ABS resin and the like.

As in Fig. 4, the piercing catheter 2 is composed of a sleeve 22 having a lumen 21 for movably holding the hooking catheter 3 and provided at a distal end with a piercing needle 25 and at a proximal end with a connector 23. The connector 23 has an inlet of the lumen 21, i.e., an insertion hole 245 for the hooking catheter 3, and is provided with a hemostatic means (or a hemostatic valve) 24 to prevent leakage of the blood during surgical operation. The hemostatic valve 24 has the same structure as that of the hemostatic valve 14 of the sheath 1, and is composed of a packing 241, a through-hole 242, a bolt-like member 243 and a nut member 244, as in Fig. 4. Further, the connector 23 is generally provided with a side injection channel 26 for injecting heparinized physiological saline into the suturing site to prevent coagulation of the blood during surgical operation. The side injection channel 26 is connected to a side injection tube 27.

The distal portion 28 of the piercing catheter 2 adjacent to the piercing needle 25 is easily bendable, and the catheter-bending means 4 is connected to the piercing needle 25. The catheter-bending means 4 can easily bend the bendable distal portion 28 of the piercing catheter 2, and the bent distal portion can be held in such a state by said catheter bending means. As the catheter-bending means 4, there may be used, for example, a wire 41 and a wire take-up device 42. The distal end of the wire 41 is fitted to the proximal end portion of the piercing needle 25, while the proximal end of the wire passes through the space between the piercing catheter 2 and the sheath 1 to be exposed outside of the proximal end of the sheath 1, and is connected to the wire take-up device 42. The wire take-up device 42 may be fitted to either the connector 13 of the sheath 1 or the connector 23 of the piercing catheter 2. Preferably, the

wire take-up means 42 is provided with a locking member which can be locked every time the wire is wound up, so as not to go back in case of letting go operator's hold. However, since the suturing operation is repeated, the locking member must be an unlockable one.

As in Fig. 6, the piercing catheter 2 is generally inserted in the lumen 11 of the sheath 1. The piercing catheter 2 is slid forward in the lumen 11 of the sheath 1, and when the top of the connector 23 of the piercing catheter 2 is brought into contact with the bottom of the connector 13 of the sheath 1, a predetermined length of the piercing needle 25 is stuck out of the sheath 1, as in Fig. 7. The length put the piercing needle 25 out of the sheath 1 is preferably such that the edge of the piercing needle 25 is fully put out.

Regarding the material of the piercing catheter 2, the sleeve 22 is preferably made of meshed or coiled stainless steel, while the connector 23 is generally made from a synthetic resin such as polypropylene, ABS resin, polyvinyl chloride, polyethylene and polyethylene terephthalate, or a metal such as stainless steel, brass or the like. Preferably, the bendable distal portion 28 may be made from a synthetic resin such as nylon, polyethylene, polyethylene terephthalate or the like, or a meshed or coiled stainless steel. The piercing needle 25 may be generally made of stainless steel such as SUS 304 or the like.

As in Fig. 5, the hooking catheter 3 is provided with a shaft 31 having a suture-hooking means 32 at a distal end, and a finger ring 33 provided on the proximal end of the shaft 31 as the manipulating element. The finger ring 33 may be made from a synthetic resin or a metal. The shaft 31 is generally made of a coiled metal wire such as stainless steel (e.g., SUS 304), tungsten, titanium or the like. Generally, the suture-hooking means 32 provided at the distal end of the shaft 31 is composed of a plurality of (generally, 3 or 4) hooking members made from wires of stainless steel (e.g., SUS 304) or a super-elastic metal (e.g., alloys of titanium-nickel, alloys containing copper and zinc, or the like). The hooking members are fixed at their proximal ends to the distal end of the shaft 31, extended outwardly and longitudinally from the shaft 31, and bent at their distal ends portion inwardly at an angle of about 90 degrees, preferably, in the range of 80 to 100 degrees to form an L-shaped hook 321. The proximal ends of the hooking members are so formed that the suture-hooking means 32 is able to expand outwardly at an angle of 15 to 30 degrees when it is stuck out of the piercing catheter 2. Because of such an arrangement, when the suture-hooking means 32 is put out of the piercing catheter 2, as in Fig. 1, the hooking members 321 do not intersect each other and can hold a suture at their hooks 321.

Using the thus-constructed catheter assembly for intracardiac suture according to the present invention, ASD atrioseptopexy is carried out in the following manner. This atrioseptopexy will be explained below, making reference to the accompanying drawings of Figs. 8 to

12.

Firstly, the catheter assembly "A" comprises the sheath 1 and the piercing catheter 2, which has been set in the state shown in Fig. 6 and in which both the top of the sheath 1 and the top of the piercing needle 25 of the piercing catheter 2 are in the same position. The catheter assembly is maneuvered into a sheath (not shown), which has been previously maneuvered into the right atrium of a patient's heart through a femoral vein of the right leg, and is introduced into the right atrium of the patient's heart. After the distal end portion of the catheter assembly "A" has been introduced into of the right atrium, the wire 41 is wound, if desired, by manipulating the wire take-up device 42 of the catheter-bending means so that the distal portion of the assembly "A" is suitably bent (in such a manner that the piercing needle 25 may be perpendicular to the interatrial septum). Thereafter the piercing needle 25 is put out of the tip of the sheath 1, as in Fig. 8, by pushing the connector 23 of the piercing catheter 2 forward by one hand, while holding the sheath 1 by the other hand. Next, the catheter assembly "A" is pushed to puncture the interatrial septum "S" with the piercing needle 25, whereby the distal end portion of the catheter assembly "A" is introduced into the left atrium, as in Fig. 9. Next, the catheter assembly "A" is further pushed until the major part of the bendable distal portion 28 of the piercing catheter 2 put into the left atrium, and the wire 41 is wound by manipulating the wire take-up device 42 of the catheter-bending means 4 while holding the piercing catheter 2 by hand, whereby the catheter assembly "A" is bent as in Fig. 10. Since the wire take-up device 42 is locked by a locking member every time the wire 41 is wound up, the catheter assembly "A" is kept bent.

While the catheter assembly "A" is kept bent, the catheter assembly "A" is pulled, whereby piercing needle pierces through the interatrial septum "S", and the distal portion of the catheter assembly "A" is introduced from the left atrium into the right atrium. Then, the piercing catheter 2 is pulled to make the piercing needle 25 accommodated in the sheath 1, and thereafter a hooking catheter 3 having a suture thread "T" as previously set therein is inserted into the catheter assembly "A" through the insertion hole 245 of the piercing catheter 2, and the suture-hooking means 32 of the hooking catheter 3 is put out of the assembly "A". In this condition, the suture thread "T" is introduced into the right atrium, and the loop "r" of the suture thread "T" is put out of the piercing catheter 2. Next, another hooking catheter 30 with no suture thread "T" is introduced into the right atrium, as in Fig. 11, which is to take up the suture thread "T" that has been brought into the right atrium in the above operation. To introduce the hooking catheter 30 into the right atrium, the hooking catheter 30 is inserted into the sheath 10 which has been maneuvered previously into the right atrium through the same or opposite femoral vein as or to the assembly "A". Next, the suture thread "T" is hooked by the suture-hooking

means 302 of the hooking catheter 30 so that the hooking catheter 30 receives the suture thread "T" from the hooking catheter 3 and brings the suture thread "T" out of the sheath 10. In that manner, one stitch is put in the interatrial septum across the defect aperture "D". Next, the suture thread "T" is ligated and cut by a suture-ligating tool (not shown), whereby the ASD atrioseptopexy is finished, as in Fig. 12. In case of two or more stitches being required, the same process as above is repeated.

As mentioned above, use of the catheter assembly for intracardiac suture of the invention makes it possible to close the affected part by direct suture, so that it can be applied to any form of the atrial septal defect. Further, it is possible to close the atrial septal defect certainly. The intracardiac suture by the catheter assembly of the invention is free from any danger since it does not leave any foreign material except the suture and since there is no separation or trouble of the devices which may occur in use of the conventional ASD devices.

Although the present invention has been fully described in connection with the preferred embodiments thereof with reference to the accompanying drawings, it is to be noted that various changes and modifications are apparent to those skilled in the art. Such changes and modifications are to be understood as included within the scope of the invention as defined by the appended claims unless they depart therefrom.

Claims

1. A catheter assembly for intracardiac suture, comprising:

a hooking catheter provided with a suture-hooking means at a distal end thereof and with a manipulating element for manipulating the suture-hooking means at a proximal end thereof;

a piercing catheter having a lumen for movably holding the hooking catheter and provided with a piercing needle at a distal end thereof and with a hemostatic means at a proximal end thereof, the distal end portion of said piercing catheter adjacent to the piercing needle being easily bendable;

a sheath having a lumen for movably holding the piercing catheter and provided with a hemostatic means at a proximal end thereof; and

a catheter-bending means connected to the piercing needle of the piercing catheter;

wherein the distal end portion of said piercing catheter can be easily bent by said catheter-bending means and the bent distal end portion can be held in such a state by said catheter bending means.

2. The catheter assembly as claimed in claim 1,

wherein said suture-hooking means comprises two or more super-elastic metal wires and formed into an L-shaped hook by bending super-elastic metal wires at the distal end portion thereof, and wherein said suture-hooking members being extended outwardly at the proximal end portion and bent inwardly at the distal end portion so that the distal portion do not intersect each other when the suture-hooking means is put out of the piercing catheter.

5

10

3. The catheter assembly according to in claim 2, wherein the distal end portion of the suture-hooking means is bent at a bend angle within the range of 80 and 100 degrees.

15

4. The catheter assembly according to any of claims 1 to 3, wherein the piercing catheter and the sheath are provided at the respective proximal ends thereof with a side injection channel for injecting heparinized physiological saline into the suturing site.

20

5. The catheter assembly according to any of claims 1 to 4, in which the catheter-bending means comprises a wire and a wire take-up means provided at the proximal end of the sheath or the piercing catheter, and wherein the distal end of the wire is fitted to the proximal end portion of the piercing needle, while the proximal end of the wire passes through the space between the piercing catheter and the sheath to be put out of the proximal end of the sheath, and is connected to the wire take-up means.

25

30

35

40

45

50

55

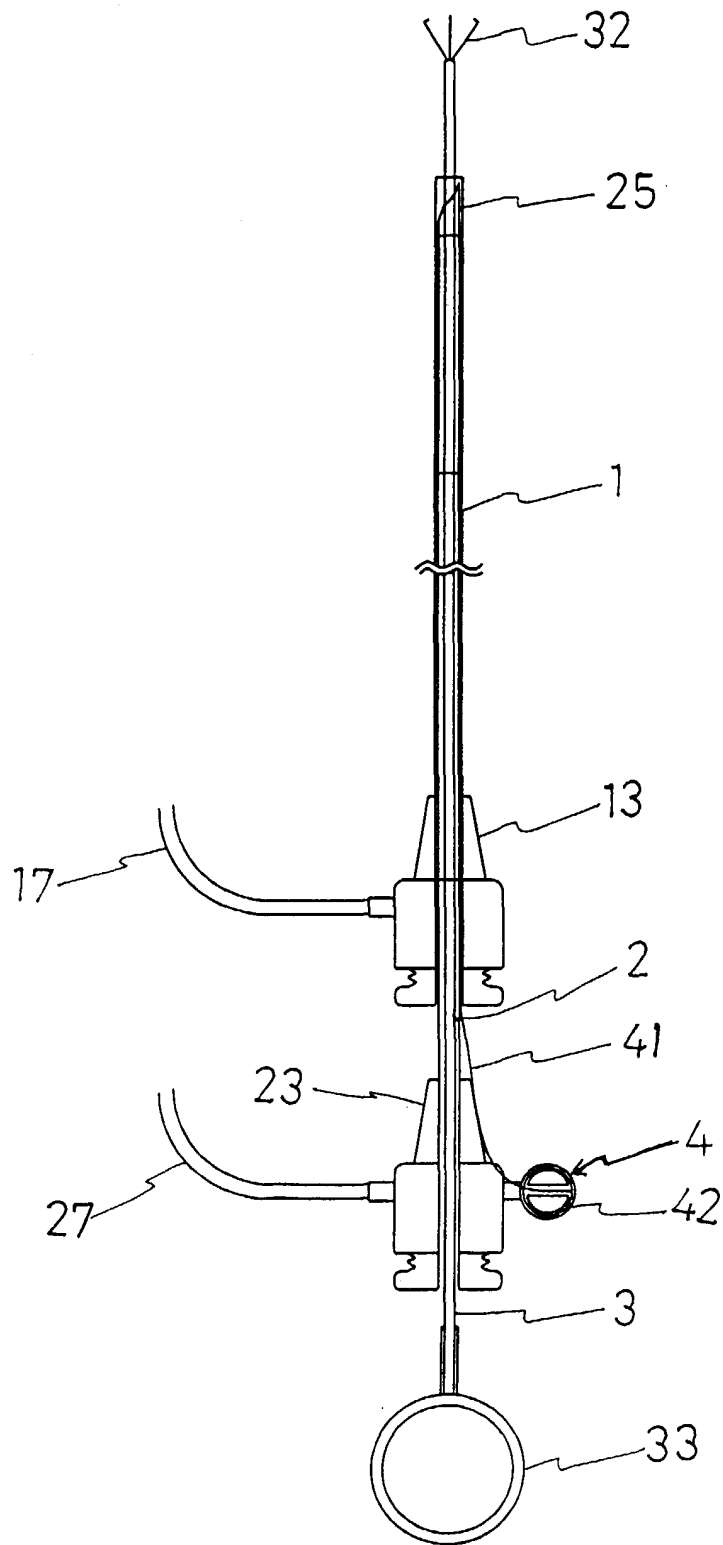


FIG. 1

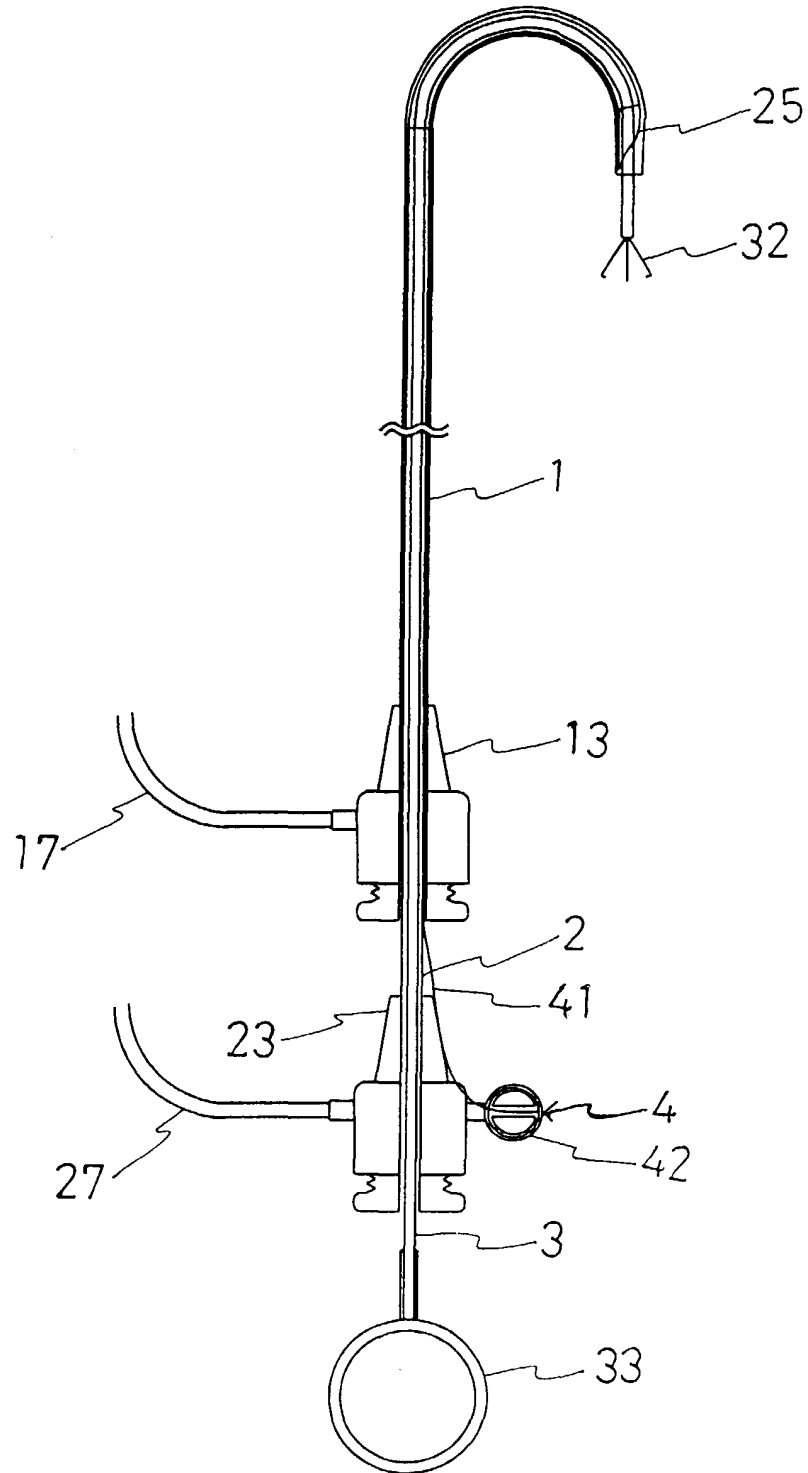


FIG. 2

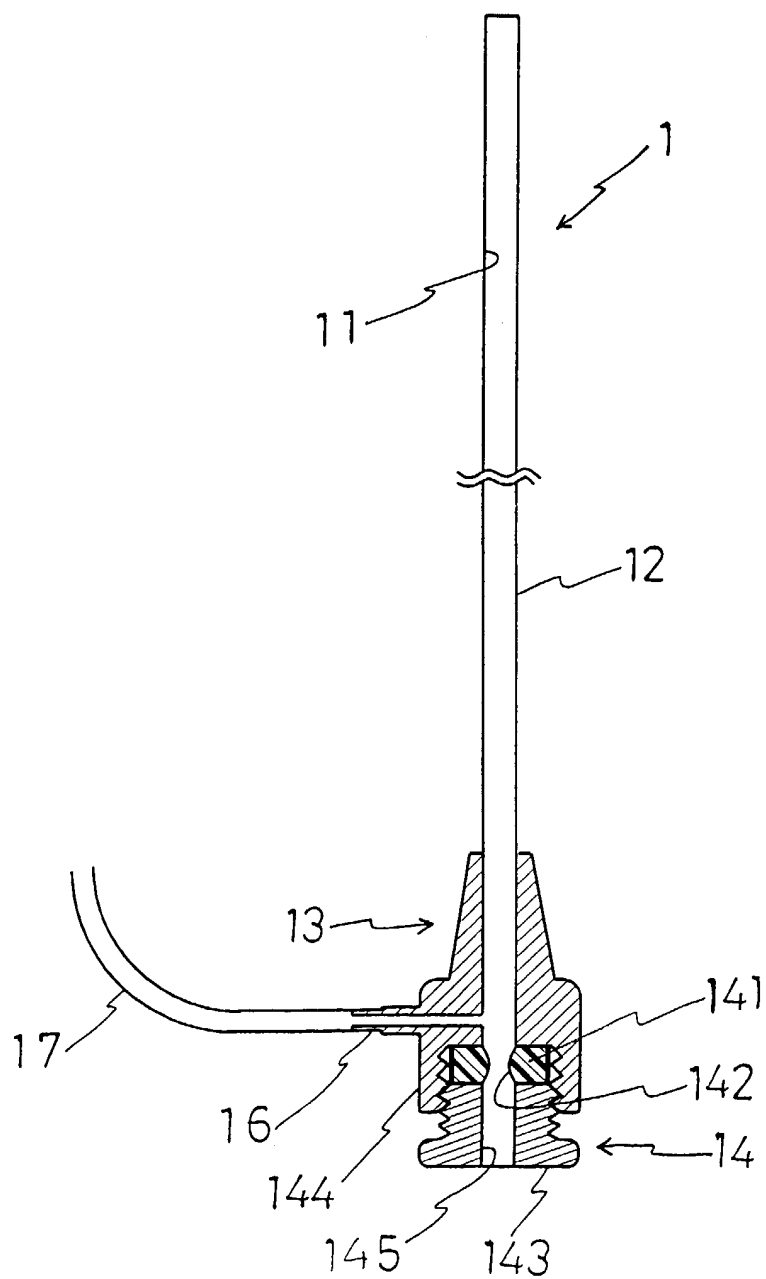


FIG. 3

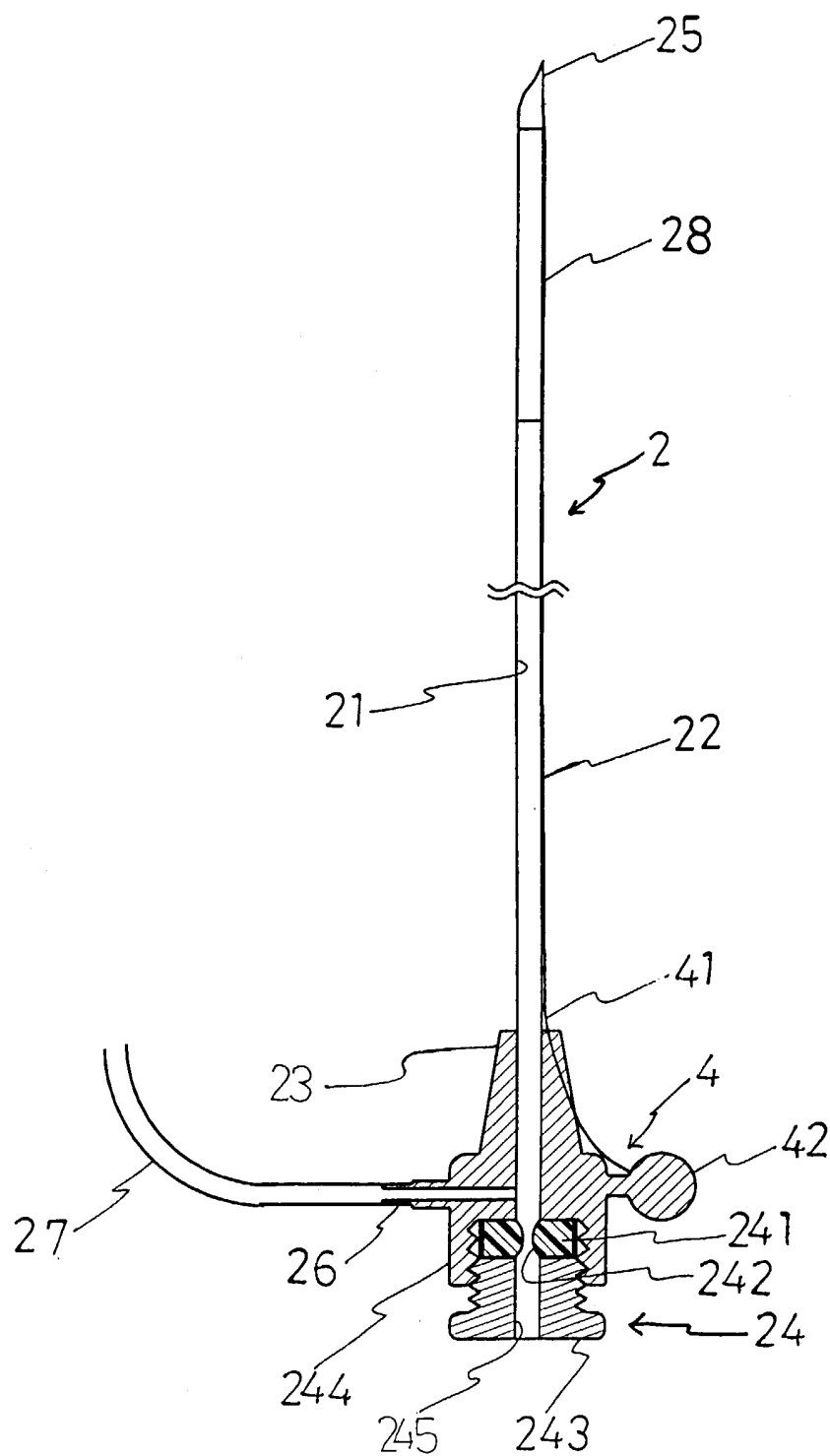


FIG. 4

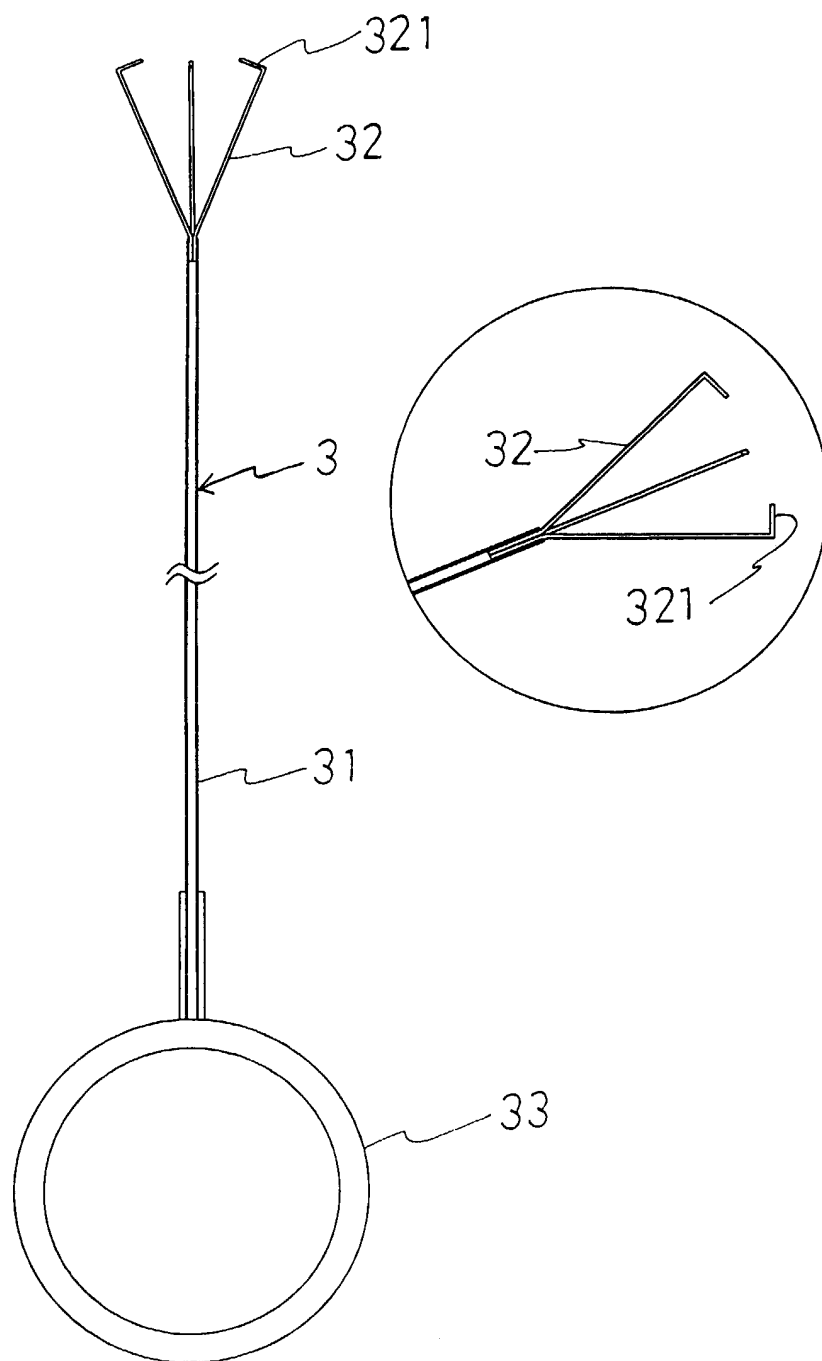


FIG. 5

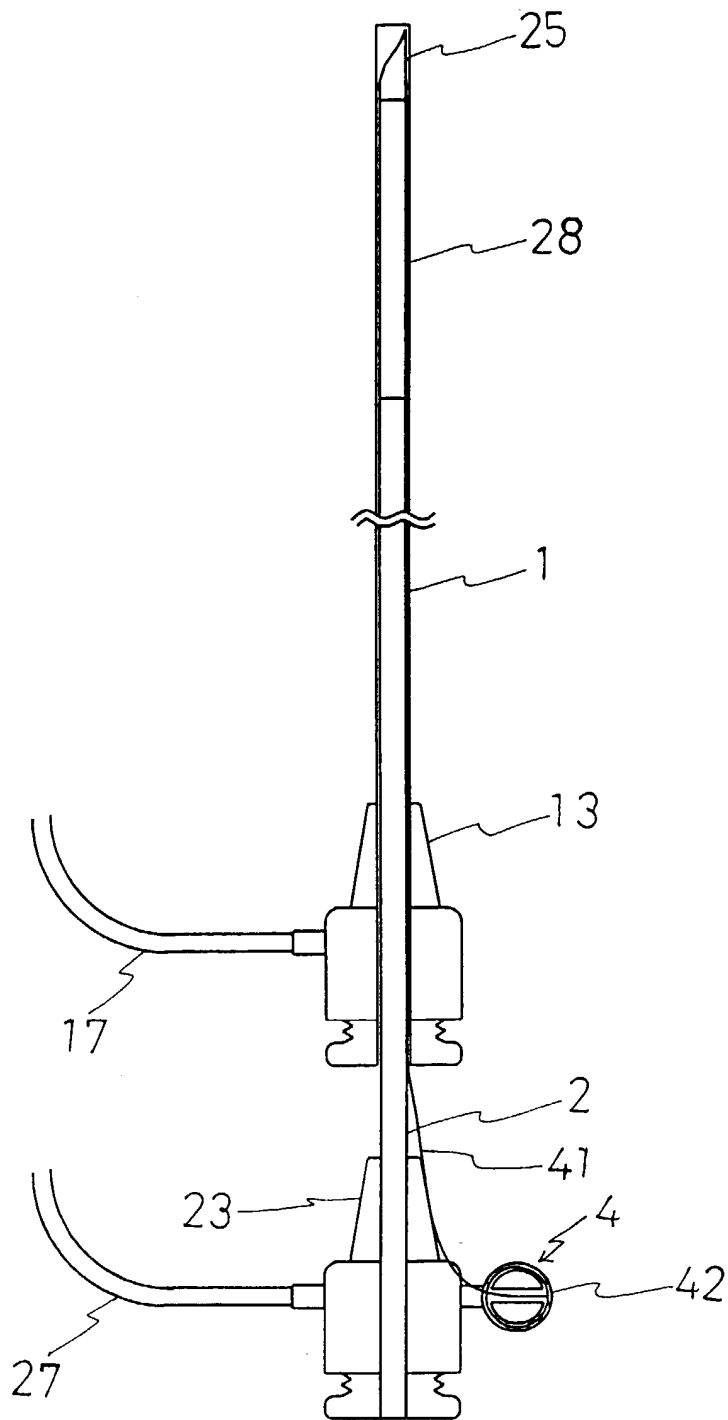


FIG. 6

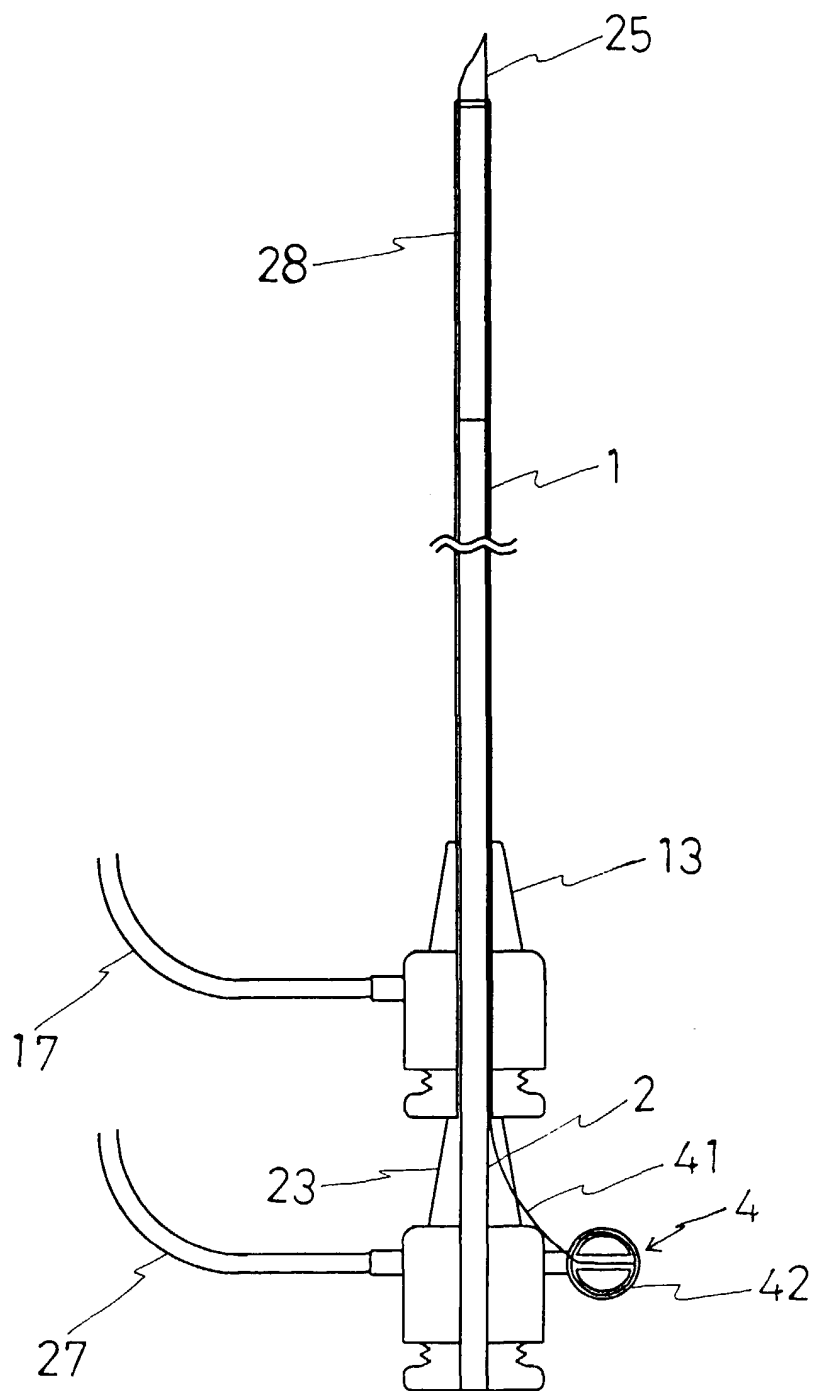


FIG. 7

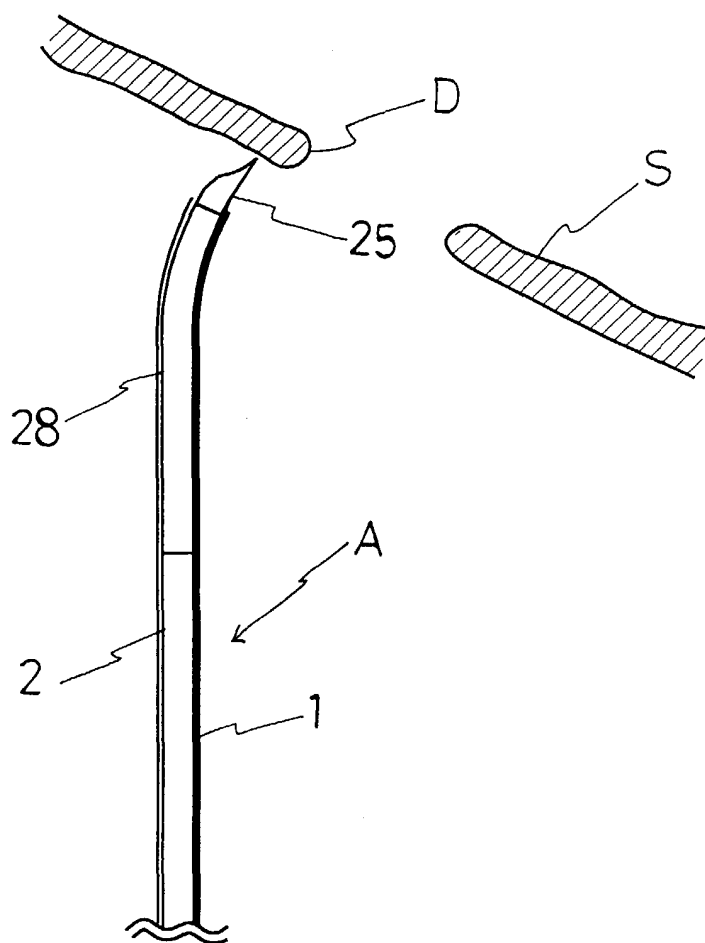


FIG. 8

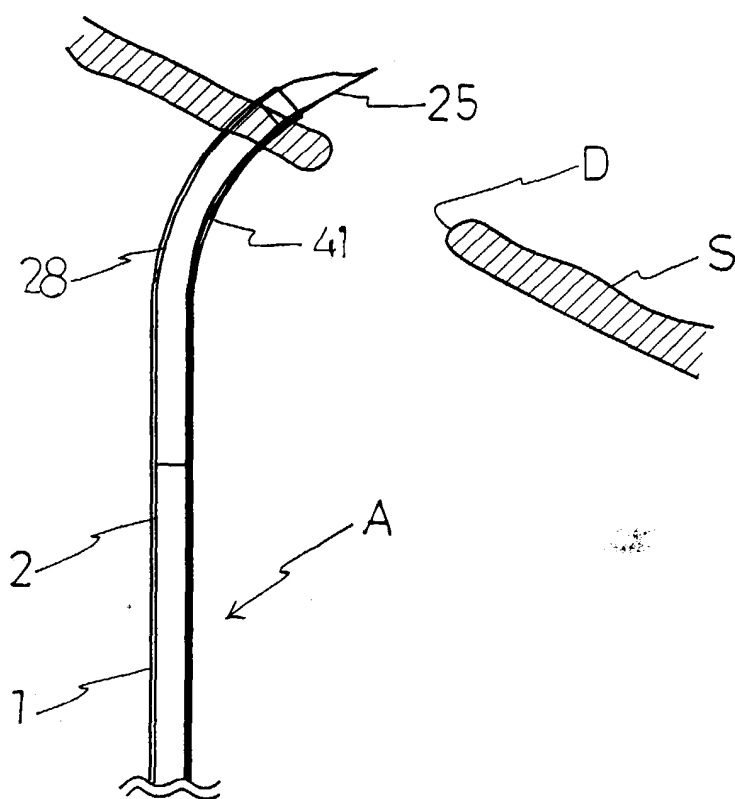


FIG. 9

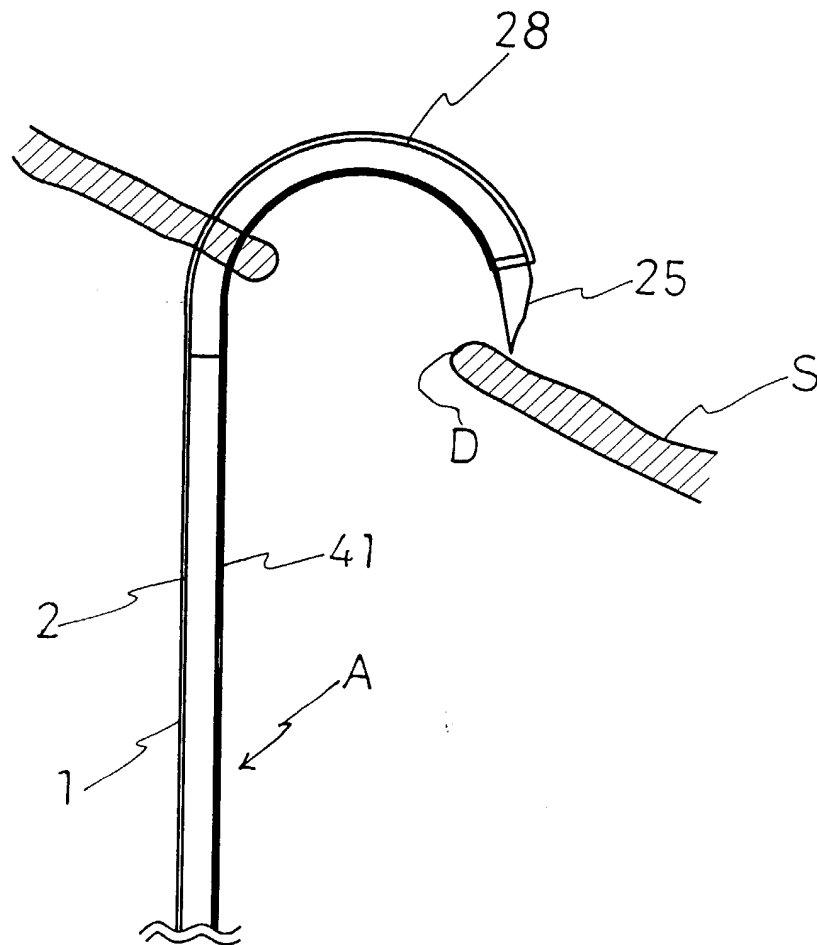


FIG. 10

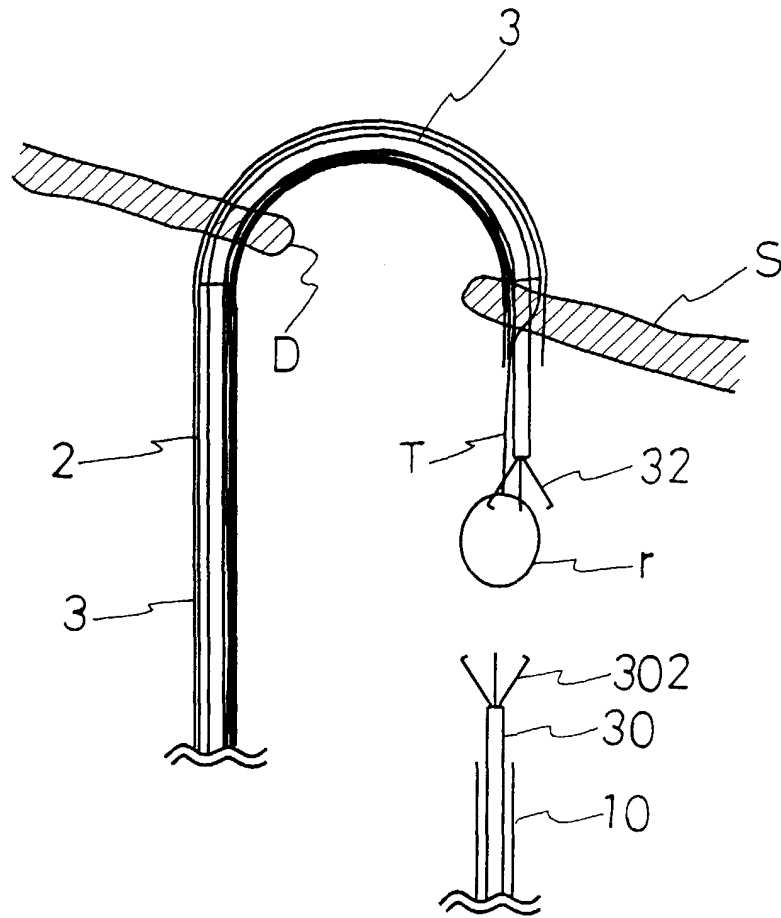


FIG. 11

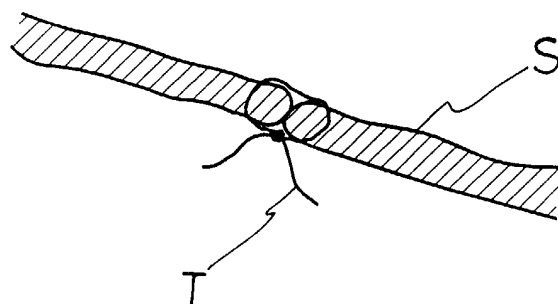


FIG. 12



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 98 10 1448

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
P,A	EP 0 769 272 A (NISSHO KK) * claims 1-5; figure 1 * ---	1	A61B17/00 A61B17/04
A	US 4 582 056 A (MCCORKLE JR CHARLES E) * figure 16B * ---	1	
A	EP 0 362 113 A (SIDERIS ELEFTHERIOS B) -----		
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
			A61B
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 22 April 1998	Examiner Gérard, B
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 03.82 (P04C01)